

II. REMARKS

The final Office Action dated March 16, 2007, has been received and carefully noted. The amendments made herein and the following remarks are submitted as a full and complete response thereto.

Claims 23-25, 27, 29, 31-66, 68-78 are pending in the present application. Claims 24, 27, 29, 34, 36, 59, 60, 62, and 74 are withdrawn from consideration by the Examiner, and Applicants reserve the right to file one or more divisional applications to the subject matter of the withdrawn claims. Applicants thank the Examiner for indicating that claims 51, 58, 61, 63-66, 71, 72 and 76 are allowable.

At this time, claims 23, 25, 35, 37, 38, 44, 47, 68-70, 73 and 75 are amended. Support for the claim amendments can be found in the specification and claims as originally filed. In particular, Applicants assert that claims 23, 25, 44, 47, 68-70, 73 and 75 are amended to optimize the Markush group, and claims 35, 37 and 38 are amended to remove language identified as inconsistent by the Examiner. Therefore, Applicants believe that no new matter is added.

Entry of this Amendment is proper under 37 C.F.R. § 1.116 since this Amendment: (a) places the application in condition for allowance for reasons discussed herein; (b) does not raise any new issues regarding further search and/or consideration since the Amendment amplifies issues previously discussed throughout prosecution; (c) does not present any additional claims without canceling a corresponding number of finally-rejected claims, and (d) places the application in better form for appeal, should an appeal be necessary. Entry of this Amendment is thus respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

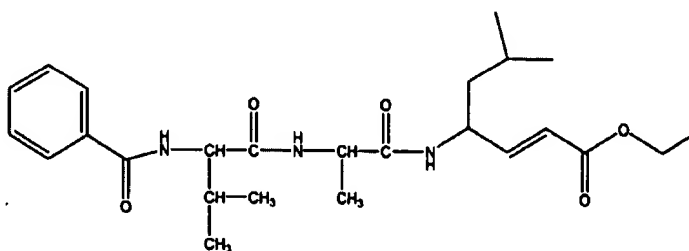
Claims 35, 37, 38-43, 45, 46, and 54 were rejected under 35 U.S.C. § 112, second paragraph, for the asserted indefiniteness. In light of the amendments to claims 35, 37, and 38, Applicants traverse the rejection.

Applicants have removed language in independent claims 35, 37 and 38 that the Examiner has cited to be inconsistent. Applicants note that claims 39-43, 45, 46 and 54 depend from claim 38. As such, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 102(a) over Johnson *et al.*

Claims 23, 25, 44, 47, 53, 68-70, 73 and 75 were rejected under 35 U.S.C. § 102(a) over Johnson *et al.* (WO 97/04004). Applicants traverse the rejection.

As noted by the Examiner, Applicants submit that Johnson *et al.* discloses the following compound:



wherein, corresponding to the present invention, R₁ is benzoyl, R₂ is hydrogen, R₃ is methyl, R₄ is methyl, and R₅ is hydrogen, R₆ is hydrogen, R₇ is methyl, and R₈ is hydrogen (Johnson *et al.*, compound 26, page 74).

Applicants submit that claims 23, 25, 44, 47, 53, 68-70, 73 and 75 are not taught or suggested by Johnson et al. For example, in contrast to Johnson et al., wherein R₁ is benzoyl, Applicants submit that present claims 23, 25, 44, 47, 68-70, and 73 are directed to a compound or pharmaceutically acceptable salt thereof of formula (I), wherein "R₁ and R₂ are independently selected from the group consisting of: H and R,..." wherein the definition of R is limited to a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton..." (emphasis added).

Applicants submit that claim 53 of the presently claimed invention is directed to a compound or pharmaceutically acceptable salt thereof in which "R₇ is a three to six carbon atom, branched alkyl group" (emphasis added). In contrast, Johnson et al. discloses a compound in which the corresponding R₇ is methyl.

Applicants submit that claim 75 of the presently claimed invention is directed to a compound or pharmaceutically acceptable salt thereof in which "R₁ and R₂ are selected from the group consisting of H and a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton..." In contrast, Applicants submit that Johnson et al. discloses a compound in which the corresponding R₁ is benzoyl.

As such, as Johnson et al. fails to teach or suggest all of the elements of the presently claimed invention, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 25, 44, 47, 53, 68-70, 73 and 75 under 35 U.S.C. § 102(a) over Johnson et al.

Rejection under 35 U.S.C. § 102(b) over Falender et al.

Claims 23, 25, 31, 44, 47, 53, 68-70, 73 and 75 were rejected under 35 U.S.C. §

102(b) over Falender et al. (Biocatalysis and Biotransformation, 13(2), 131-139 (1995)).

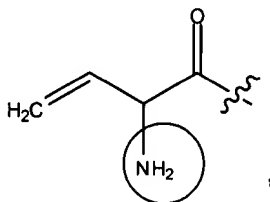
Applicants traverse the rejection.

As noted by the Examiner, Applicants submit that Falender et al. discloses the following compound:



wherein, corresponding to the presently claimed invention, R₁ is allylglycine, R₂ is hydrogen, R₃ is phenyl, R₄ is hydrogen, R₅ is hydrogen, R₆ is hydrogen, R₇ is benzyl, and R₈ is hydrogen.

In contrast, Applicants submit that claims 23, 25, 31, 44, 47, 53, 68-70, 73 and 75 are not taught or suggested by Falender et al. For example, present claims 23, 25, 44, 47, 68-70, and 73 are directed to a compound or pharmaceutically acceptable salt thereof of formula (I), wherein "R₁ and R₂" are independently selected from the group consisting of: H and R,... wherein the definition of R is limited to a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton containing one to ten carbon atoms, and the carbon atoms are optionally substituted with: -OH, -I, -Br, -Cl, -F, -CN, -CO₂H, -CHO, -COSH, or -NO₂. As mentioned above, Falender et al. discloses that R₁ is allylglycine and R₂ is hydrogen. Applicants note that allylglycine has the following structure:



wherein, as circled, the moiety is substituted with -NH₂. Applicants submit that the compounds of present claims 23, 25, 44, 47, 68-70, and 73 are not directed to compounds in which R₁ or R₂ is substituted with -NH₂.

Applicants submit that claim 31 is directed to a compound or pharmaceutically

acceptable salt thereof in which “R₃ and R₄ are independently selected from the group consisting of: methyl, ethyl, n-propyl and n-butyl” and “R₅ is selected from the group consisting of: H, R, ArR-, and Ar” (emphasis added). In contrast, Falender et al. discloses a compound in which the corresponding R₃ is phenyl, and R₄ and R₅ are both hydrogen.

Further, Applicants submit that claim 53 is directed to a compound in which “R₇ is a three to six carbon atom, branched alkyl group” (emphasis added). In contrast, Falender et al. discloses a compound in which the corresponding R₇ is a benzyl group.

Applicants submit that claim 75 of the presently claimed invention is directed to a compound or pharmaceutically acceptable salt thereof in which “R₁ and R₂ are selected from the group consisting of H and a saturated or unsaturated moiety... containing one to ten carbon atoms...and the carbon atoms are optionally substituted with -OH, -I, -Br, -Cl, -F, -CN, -CO₂H, -CHO, -COSH, and - NO₂.” In contrast, Applicants submit that Johnson et al. discloses a compound in which the corresponding R₁ is allylglycine, which is a moiety containing -NH₂.

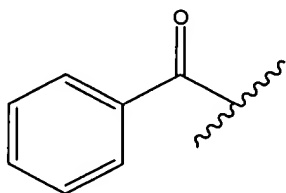
As such, as Falender et al. does not teach or suggest all of the elements of the presently claimed invention, Applicants request reconsideration and withdrawal of the rejection of claims 23, 25, 31, 44, 47, 53, 68-70, 73 and 75 under 35 U.S.C. § 102(b) over Falender et al.

Rejection under 35 U.S.C. § 103 over Johnson et al.

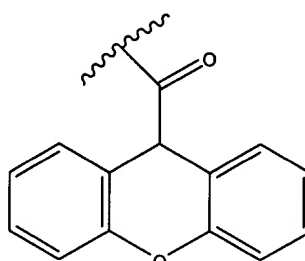
Claims 23, 25, 44, 47, 53, 68-70, 73, 75, 77 and 78 were rejected under 35 U.S.C. § 103 over Johnson et al. Applicants traverse the rejection.

Applicants have discussed the differences between the presently claimed invention and the compound disclosed in Johnson et al. above. Applicants submit that the compounds and

pharmaceutically acceptable salts thereof disclosed in present claims 23, 25, 44, 47, 53, 68-70, 73, 75, 77 and 78 are not structurally similar to the compound disclosed in Johnson et al. As such, Applicants submit that one of ordinary skill in the art would not be motivated to modify the compound disclosed in Johnson et al. to arrive at the presently claimed invention without the benefit of hindsight. For example, compound 26 of Johnson et al. and compound 34 of Johnson et al., which was previously cited against the present application, both require bulky ring structures at the R₁ and R₂ positions:



R₁ Johnson et al. Compound 26



R₁ Johnson et al. Compound 34

In contrast, in present claims 23, 25, 44, 47, 53, 68-70, and 73, R₁ and R₂ are selected from "the group consisting of: H and R, provided that neither R₁ or R₂ is tert-butoxycarbonyl, wherein the definition of R is limited to a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton containing one to ten carbon atoms..." (emphasis added).

Similarly, present claim 75 is directed to a compound or pharmaceutically acceptable salt thereof in which "R₁ and R₂ are selected from the group consisting of H and a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton..." Claims 77 and 78 depend from claim 75.

As such, Applicants submit that Johnson et al. does not teach or suggest modifying the compound disclosed in Johnson, particularly R₁ and R₂, by replacing the bulky ring structures

with the R₁ and R₂ structures of the presently claimed invention.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 25, 44, 47, 53, 68-70, 73, 75, 77 and 78 under 35 U.S.C. § 103 over Johnson *et al.*

Rejection under 35 U.S.C. § 103 over Falender *et al.*

Claims 23, 25, 31, 44, 47, 53, 68-70, 73, 75, 77 and 78 were rejected under 35 U.S.C. § 103 over Falender *et al.* Applicants traverse the rejection.

Applicants have discussed the differences between the compound disclosed in Falender *et al.* and the presently claimed invention above. Applicants submit that present claims 23, 25, 31, 44, 47, 53, 68-70, 73, 75, 77 and 78 are patentable over Falender *et al.*, because without the benefit of hindsight, one of ordinary skill in the art would not be motivated to modify the compound disclosed in Falender *et al.* to arrive at the presently claimed invention. In particular, Applicants submit that Falender *et al.*, which is merely directed to the synthesis of tetrapeptide ethylesters, fails to provide guidance as to which groups are necessary to impart biological activity, a property of the presently claimed compounds and pharmaceutically acceptable salts thereof (see specification, page 12, line 20). Applicants submit that since Falender *et al.* does not teach or suggest how such properties can be attained, there can be no motivation to modify this reference towards Applicants' solution.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 25, 31, 44, 47, 53, 68-70, 73, 75, 77 and 78 under 35 U.S.C. § 103 over Falender *et al.*

III. CONCLUSION

In view of the amendments and remarks above, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to discuss any remaining issues.

Any additional fees that are required with respect to this response may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 108281-00000.

Respectfully submitted,

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